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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/705,281	11/10/2003	Vesselin Danailov Miladinov	1084.0100	4913

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EXAMINER

TATE, CHRISTOPHER ROBIN

ART UNIT	PAPER NUMBER
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1655

DATE MAILED: 09/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/705,281

Applicant(s)

MILADINOV ET AL.

Examiner

Christopher R. Tate

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9-12 is/are allowed.
- 6) ☒ Claim(s) 1-8 and 13-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The amendment filed 28 July 2005 is acknowledged and has been entered. Claims 1-20 have been examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8 and 13-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In independent claims 1 and 13, the newly recited phrase "wherein protein is a sole dietary source of metabolic energy in said mixture" is deemed new matter. The examiner could find no support in the instant specification for this newly recited limitation and Applicants did not particularly point to support therein in their 28 July 2005 response.

Applicant is required to cancel the new matter in the reply to this Office Action or, alternatively, particularly point to support of this limitation within the instant specification.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, first paragraph for the reasons set forth above.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 and 13-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claims 1 and 13 are rendered vague and indefinite by the newly recited phrase "wherein protein is a sole dietary source of metabolic energy in said mixture". This ambiguous phrase is indefinite and unclear - e.g., what protein are these claims attempting to define: the whey protein, the protein within calcium caseinate, the protein within the food to which the supplement is added, or something else? Also, how can the protein be the only source of metabolic energy within the mixture? It does not seem feasible that other non-protein components (e.g., L-carnitine, calcium, etc) would not provide any "metabolic energy" to the mixture since they too would necessarily be metabolized by the body (and thus provide some energy) upon ingestion.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

### ***Claim Rejections - 35 USC § 103***

Claims 1-7 and 13-19 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Lowry et al. (US 6,376,544) in view of Mulchandani et al. (US 5,108,767) for the reasons set forth in the previous Office action which are restated below.

Lowry et al. beneficially teach homogenized nutrient compositions for providing essential nutrients to a person having renal failure which beneficially comprise arginine, a typical (preferred) protein source such as calcium caseinate and whey protein, as well as other optional nutrients such as carnitine therein. Lowry et al. further disclose that the protein source can be any suitable protein and/or amino acid mixture (see entire document including, e.g., col 4, line 48 – col 6, line 51; Examples; Claims). Lowry et al. do not expressly teach the incorporation of L-carnitine therein.

Mulchandani et al. also teach homogenized nutrient compositions for providing essential nutrients to a person having renal failure which beneficially comprise a protein source such as calcium caseinate (containing arginine – based upon an amino acid profile), and L-carnitine therein. Mulchandani et al. further disclose that renal patients may have low plasma carnitine levels as well as elevated serum triglyceride levels. Therefore, Mulchandani et al. advantageously teach that L-carnitine supplementation helps replete plasma carnitine pools and may help lower triglyceride levels in these patients. (see, e.g., col 5, line 8 – col 6, line 57; col 8, lines 7-45; col 12, lines 30-57; col 14, line 62 – 15, line 3; and claims).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to prepare a composition (supplement) designed to provide essential nutrients to a person having renal failure comprising a homogenous mixture of calcium caseinate, whey protein, L-carnitine, and arginine therein based upon the beneficial teachings provided by the cited references, as discussed above. The result-effective adjustment of particular conventional working conditions (e.g., determining result-effective amounts and/or ratio ranges of less-than-all of the recited ingredients therein - such as the ratios of only some,

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but not all, of the claimed ingredients as recited in claims 2-7 and 14-19; as well as to exclude certain components such as a lipid source therefrom) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan having the cited references before him/her, especially since it is well recognized in the nutrient art to tailor such nutrient formulations (with respect to such amounts/ratios; as well as exclusion or inclusion of a certain dietary source such as lipid therefrom) based upon individual need.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicants' arguments concerning the above USC 103 rejection have been carefully considered but are not deemed to be persuasive of error in the rejection. Applicants argue that the Lowry et al. in view of Mulchandani et al. fail to teach or suggest all of the claim limitations including the newly recited claim limitation "wherein protein is a sole dietary source of metabolic energy in said mixture". However (notwithstanding the USC 112 rejections concerning this phrase), as discussed above, it is reemphasized that it would have been obvious to provide essential nutrients to a person having renal failure comprising a homogenous mixture of calcium caseinate, whey protein, L-carnitine, and arginine therein based upon the beneficial teachings provided by the cited references - including providing a nutrient composition containing only calcium caseinate and whey protein as metabolic protein sources, as well as to exclude a particular component therefrom such as a lipid source, based upon individual need.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

### **Conclusion**

Claims 9-12 are allowed. Please also note that claims 8 and 20 (which, based upon dependency, fully recite the weight ratio of each essential ingredient to the other therein) would be allowable provided the claims be amended so as to overcome the USC 112, first and second paragraph rejections above; and that they be rewritten in independent form including all of the limitations of the respective base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, consisting of several overlapping loops and a final horizontal stroke.

Christopher R. Tate  
Primary Examiner  
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